4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2007-D-0369, FDA-2008-D-0610, FDA-2015-D-1211, FDA-2021-D-0409, FDA-2020-D-0987, FDA-2020-D-1057, FDA-2020-D-1106, FDA-2020-D-1106-0002, FDA-2020-D-1108, FDA-2020-D-1136, FDA-2020-D-1137, FDA-2020-D-1138, FDA-2020-D-1139, FDA-2020-D-1140, FDA-2020-D-1304, FDA-2020-D-1370, FDA-2020-D-1386, FDA-2020-D-1414, FDA-2020-D-1824, FDA-2020-D-1825, FDA-2020-D-2016, FDA-2021-D-1311]

Guidance Documents Related to Coronavirus Disease 2019 (COVID-19)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: On February 9, 2023, the Secretary of Health and Human Services (HHS) renewed the Coronavirus Disease 2019 (COVID-19) public health emergency declaration issued under section 319 of the Public Health Service Act (PHS Act) ("PHE declaration"), effective February 11, 2023. The declaration is expected to expire at the end of the day on May 11, 2023. The Food and Drug Administration (FDA, Agency, or we) has issued guidance documents to address the circumstances of the public health emergency and, more generally, COVID-19. Many of those guidance documents are tied to the duration of the PHE declaration. This notice is intended to provide clarity to stakeholders with respect to the guidance documents that will no longer be effective with the expiration of the PHE declaration and the guidances that FDA is revising to continue in effect after the expiration of the PHE declaration.

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SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID-19, and after consultation with public health officials as necessary, the prior Secretary of HHS, pursuant to the authority under section 319 of the PHS Act (42 U.S.C. 247d), determined that a PHE existed (COVID-19 PHE) and had existed since January 27, 2020, nationwide.[1] On February 9, 2023, the Secretary of HHS renewed the COVID-19 PHE declaration, effective February 11, 2023. On February 9, based on current COVID-19 trends, HHS announced that it is planning for the declaration to expire at the end of the day on May 11, 2023. (HHS, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap (February 9, 2023), available at https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html#:~:text=Based%20on%20current%20COVID%2D19,day%20on%20May%2011%2C%202023)

[1] Secretary of HHS, "Determination that a Public Health Emergency Exists" (originally issued on January 31, 2020, and subsequently renewed, pursuant to the authority under section 319 of the PHS Act), available at: https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx. There are additional types of determinations and declarations related to emergencies, including public health emergencies, that are distinct from a PHE declared pursuant to section 319 of the PHS Act. For instance, the determination and declarations made under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which enable the issuance of Emergency Use Authorizations (EUAs), are independent from a declaration under section 319 of the PHS Act.

Since the start of the COVID-19 pandemic in 2020, FDA has issued more than 80 COVID-19-related guidances (not including revisions). In the *Federal Register* of March 25, 2020 (85 FR 16949) (available at https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf), FDA announced general procedures for making available FDA guidances related to the COVID-19 PHE. We have updated or otherwise modified our COVID-19-related guidances in response to comments received, as appropriate, and as relevant needs and circumstances evolved throughout the COVID-19 PHE. We have withdrawn, and announced the withdrawal of, several COVID-19-related guidances after determining that the policies no longer represented the Agency's current thinking.[2] In December 2021, we issued a draft guidance "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency" ("draft device enforcement policy transition guidance") that describes FDA's proposed plans for devices that fall within the enforcement policies of certain device guidances issued during the COVID-19 PHE.[3] FDA intends to finalize the draft guidance as soon as practicable. In the *Federal Register* of December 8, 2022 (87 FR 75275), FDA announced the availability of a final guidance "Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria," which replaced the COVID-19-related guidance FDA issued in April 2020, and is available at https://www.fda.gov/media/163737/download.

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[2] See 86 FR 55620 (October 6, 2021), available at https://www.federalregister.gov/documents/2021/10/06/2021-21798/guidance-documents-related-to-coronavirus-disease-2019-availability; 86 FR 56960 (October 13, 2021), available at https://www.federalregister.gov/documents/2021/10/13/2021-22108/alcohol-based-hand-sanitizer-products-withdrawal-of-three-temporary-guidance-documents-issued-during; 87 FR 34691 (June 7, 2022), available at https://www.federalregister.gov/documents/2022/06/07/2022-12176/effects-of-the-covid-19-public-health-emergency-on-formal-meetings-and-user-fee-applications-for; 87 FR 78111 (December 21, 2022), available at https://www.federalregister.gov/documents/2022/12/21/2022-27673/enforcement-policy-regarding-federal-veterinarian-client-patient-relationship-requirements-to; 88 FR 8872 (February 10, 2023), available at https://www.federalregister.gov/documents/2023/02/10/2023-02809/temporary-policy-on-repackaging-or-combining-propofol-drug-products-during-the-covid-19-public. In addition, one guidance document entitled "Policy for Certain REMS Requirements During the Tocilizumab Shortage Related to the COVID-19 Public Health Emergency" stated it would "remain in effect for the duration of the tocilizumab shortage"; because the tocilizumab shortage resolved on March 30, 2022, the guidance is no longer in effect (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/withdrawn-guidances-biologics).

[3] See 86 FR 72973 (December 23, 2021). Concurrent with issuance of the draft device enforcement policy transition guidance, FDA also issued "Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the COVID-19 Public Health Emergency," which described and sought comment on FDA's general recommendations for a transition for devices issued EUAs. See 86 FR 72978 (December 23, 2021). FDA also intends to finalize this guidance as soon as practicable.

Circumstances have changed since 2020 when FDA first began issuing guidances to support COVID-19 response efforts. For example, several COVID-19 guidances were developed to help address supply chain disruptions. In several instances, supply chains have stabilized and the relevant COVID-19 guidances are no longer needed. Some COVID-19 guidances were issued to clarify previously issued recommendations by tailoring them to specific considerations for the pandemic. Because these COVID-19 guidances will not be needed when the PHE declaration expires, FDA is not extending them. In other instances, the science behind certain recommendations has advanced, and FDA may want to update certain guidances to reflect new data.

This notice addresses the 72 COVID-19-related guidance documents that are currently in effect and listed below. Most of these COVID-19-related guidances state that they are intended to remain in effect only for the duration of the COVID-19 PHE declaration. In light of HHS's recent announcement that the PHE declaration is expected to expire on May 11, 2023, FDA has reviewed these COVID-19-related guidance documents and has examined whether any of the guidances should be continued past expiration of the PHE declaration--for example, to provide stakeholders including industry, healthcare providers, patients, consumers, and FDA time to transition from policies adopted and operations implemented during the COVID-19 PHE.

Based on this review, in this notice, FDA is announcing that the COVID-19-related guidances listed in section II, table 1 will no longer be in effect when the PHE declaration expires. FDA also is announcing that the COVID-19-related guidance documents listed in section III, table 2 of this notice are being revised to continue in effect for 180 days after the PHE declaration expires, then will no longer be in effect. The guidance documents listed in section IV, table 3 of this notice are being revised to continue in effect for 180 days after the PHE declaration expires, during which time FDA plans to further revise these guidances. Finally, this notice lists, in section V, table 4, COVID-19-related guidance documents whose intended

duration is not tied to the COVID-19 PHE and that will remain in effect when the COVID-19 PHE declaration expires.

FDA's revision of the guidances in section III, table 2 and section IV, table 3 so that they continue in effect for a brief period after expiration of the PHE declaration constitutes a minor change under 21 CFR 10.115(c)(2) and (g)(4). Even if these revisions were not minor changes, FDA has determined that obtaining comment prior to implementation is not feasible or appropriate, given the need for an orderly transition and given that the PHE declaration is anticipated to expire on May 11, 2023. Moreover, FDA already has solicited comments on these policies, through dockets for the guidances, and we have taken the comments received into account in issuing this notice. This period of time will provide an opportunity for stakeholders to transition from policies adopted and operations implemented during the COVID-19 PHE (see section III, table 2 below) or for FDA to further revise or otherwise update the guidance (see section IV, table 3 below). Although the changes to continue the guidances in section III, table 2 and section IV, table 3 for a brief period after the PHE declaration expires are being implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate.

As the COVID-19 pandemic evolves, FDA continues to assess the needs and circumstances related to the policies in our COVID-19-related guidances, and we may alter our approach for individual guidances listed in this notice. For instance, FDA could withdraw a guidance before the COVID-19 PHE declaration expires should reassessment show policy reflected in a particular guidance document is no longer needed. However, should FDA alter our approach for particular guidances, we will do so consistent with our good guidance practices regulation (21 CFR 10.115).

II. COVID-19 Guidance Documents That Will No Longer Be in Effect Upon Expiration of the COVID-19 PHE Declaration

FDA has identified 22 COVID-19-related guidances that should no longer be in effect upon expiration of the COVID-19 PHE declaration. Most of these guidances state that they are intended to remain in effect only for the duration of the declared COVID-19 PHE. FDA has assessed the needs and circumstances related to the policies articulated in the 22 guidances listed in table 1. FDA also has considered comments submitted to the dockets for these guidances, and our experience with implementation. Upon review, FDA continues to believe that it is appropriate for these guidances to end when the PHE declaration expires.

While generally intended to be in effect for the duration of the COVID-19 PHE declaration, five guidances listed in table 1 also indicated that FDA expected their recommendations would continue to assist the Agency and/or stakeholders outside the expiration of the PHE declaration, otherwise reflected FDA's current thinking, or were proposed to be extended in the draft device enforcement policy transition guidance. Upon assessment of these guidances, FDA has found that these will no longer be needed because the recommendations are described in other guidance documents or the conditions related to the COVID-19 PHE as outlined in the guidances have changed and stakeholders have resumed or adjusted operations and are no longer relying on the guidances. Therefore, FDA has concluded it is appropriate for these five guidances, marked with an asterisk in table 1, to end upon expiration of the PHE declaration.

Table 1.--Guidance Documents that Will No Longer Be in Effect Upon Expiration of the COVID-19 PHE Declaration

Docket No.	Lead Center	Title of Guidance
FDA-2020-D-1137	CBER	Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency
FDA-2020-D-1136	CDER	COVID-19 Public Health Emergency Policy on COVID-19-Related Sanitation Tunnels
FDA-2021-D-1311	CDER	Nonclinical Considerations for Mitigating Nonhuman Primate Supply Constraints Arising from the COVID-19 Pandemic*
FDA-2020-D-1136	CDER	Development of Abbreviated New Drug Applications During the COVID-19 Pandemic--Questions and Answers
FDA-2020-D-1136	CDER	Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency

FDA-2020-D-1136	CDER	Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency Guidance for Industry
FDA-2020-D-1136	CDER	Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency*
FDA-2020-D-1136	CDER	Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing*
FDA-2020-D-1136	CDER	Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency
FDA-2020-D-1136	CDER	Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications--Questions and Answers
FDA-2020-D-1136	CDER	Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency
FDA-2020-D-1136	CDER	Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry
FDA-2020-D-1136	CDER	Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency
FDA-2020-D-1136	CDER	Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency*
FDA-2020-D-1136	CDER	COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products
FDA-2020-D-1136	CDER	Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency[4]
FDA-2020-D-1138	CDRH	Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised)
FDA-2020-D-1138	CDRH	Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 Public Health Emergency*
FDA-2020-D-1139	CFSAN	Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID-19 Public Health Emergency
FDA-2020-D-1139	CFSAN	Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID-19 Public Health Emergency
FDA-2020-D-1139	CFSAN	Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency
FDA-2020-D-1139	CFSAN	Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID-19 Public Health Emergency

III. COVID-19 Guidance Documents that FDA is Revising to Continue in Effect for 180 Days After the PHE Declaration Expires to Provide a Period for Stakeholder Transition

[4] While the guidance document entitled "Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency" will no longer be in effect when the COVID-19 PHE declared under section 319 of the PHS Act expires, the Agency retains authority under section 582(a) of the FD&C Act (21 U.S.C. 360eee-1(a)) to grant waivers, exemptions, and exceptions to allow for continued distribution of covered COVID-19 Drug Supply Chain Security Act products, as appropriate, which may be used to avoid disruption beyond the expiration of such declaration.

Based on our review, FDA has identified 22 COVID-19-related guidances that, similar to the guidances previously discussed, can be discontinued in connection with expiration of the COVID-19 PHE declaration but for which an additional wind-down period is appropriate to allow for an orderly transition. In general, these guidances were intended to be in effect for the duration of the declared COVID-19 PHE. However, FDA has considered the circumstances surrounding the current phase of the COVID-19 pandemic, comments submitted to the dockets for these guidances, and our experience with implementation, and has determined that for these guidances, stakeholders such as industry, healthcare providers, patients, consumers, and FDA would benefit from additional time to transition from the policies adopted during the COVID-19 PHE. Thus, FDA is revising the 22 guidances listed in table 2 to continue in effect for 180 days after the expiration of the PHE declaration--i.e., after November 7, 2023, they will no longer be in effect. We note that some of these guidances are addressed in the draft device enforcement policy transition guidance, which, when finalized, may specify a duration period for these guidances that is longer than the time period described here. Therefore, the guidances listed in table 2 are being revised to reflect that they continue in effect for 180 days after the COVID-19 PHE declaration expires, with the exception of guidances covered under the draft device enforcement policy transition guidance. Those device guidances, which are identified in table 2 with an asterisk, are being revised to reflect that they continue in effect for 180 days after expiration of the PHE declaration unless a different intended duration for the guidance is set forth in the final device transition guidance.

Table 2.--Guidance Documents FDA is Revising to Continue in Effect for 180 Days After the COVID-19 PHE Declaration Expires

Docket No.	Lead Center	Title of Guidance
FDA-2020-D-1136	CDER	Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94(e)(1) For Oxygen and Nitrogen During the COVID-19 Public Health Emergency Guidance for Industry
FDA-2020-D-1136	CDER	Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers
FDA-2020-D-1106	CDER	Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals
FDA-2020-D-1138	CDRH	Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*

FDA-2020-D-1138	CDRH	Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*[5]
FDA-2020-D-1138	CDRH	Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
FDA-2020-D-1138	CDRH	Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)*
FDA-2020-D-1138	CDRH	Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)*
FDA-2020-D-1139	CFSAN	Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency
FDA-2020-D-1139	CFSAN	Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines
FDA-2020-D-1386	CFSAN	Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
FDA-2020-D-1140	CVM	CVM GFI #270 - Guidance on the Conduct and Review of Studies to Support New Animal Drug Development during the COVID-19 Public Health Emergency

[5] FDA is revising the guidance "Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)" to split it into two separate guidance documents, each with identical policies to the corresponding parts of the September 2021 version. Concurrent with issuance of this guidance addressing face shields, surgical masks, and respirators, FDA also is issuing "Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency." That guidance is listed in table 3 of this notice.

IV. COVID-19 Guidance Documents FDA is Revising to Continue in Effect for 180 Days After Expiration of the PHE Declaration, During Which Time FDA Plans to Further Revise the Guidances

Based on our review, FDA has identified 24 COVID-19-related guidances that we intend to retain with appropriate changes after expiration of the COVID-19 PHE declaration. Therefore, FDA is revising the 24 guidances listed in table 3 to continue in effect for 180 days after the COVID-19 PHE declaration expires. During that time, FDA plans to further revise each of these guidances with any appropriate changes based on comments received and the Agency's experience with implementation. For example, FDA could revise a guidance so its duration aligns with an applicable declaration made under section 564 of the FD&C Act enabling the issuance of EUAs, or by removing language describing intended duration. Once a revised final guidance is issued, which could occur sooner than 180 days after the PHE declaration expires, it will supersede the guidance listed in table 3.

Table 3.--Guidance Documents FDA is Revising to Continue in Effect for 180 Days After the PHE Declaration Expires, During Which Time FDA Plans to Further Revise the Guidances

Docket No.	Lead Center	Title of Guidance
FDA-2020-D-1137	CBER	Emergency Use Authorization for Vaccines to Prevent COVID-19
FDA-2020-D-1825	CBER	Investigational COVID-19 Convalescent Plasma
FDA-2015-D-1211	CBER	Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products
FDA-2020-D-1137	CBER	Development and Licensure of Vaccines to Prevent COVID-19
FDA-2020-D-1137	CBER	Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency
FDA-2020-D-1106-0002	CDER	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency
FDA-2020-D-1370	CDER	COVID-19: Developing Drugs and Biological Products for Treatment or Prevention
FDA-2020-D-2016	CDER	Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the COVID-19 Public Health Emergency (COVID-19)
FDA-2020-D-1136	CDER	COVID-19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS-CoV-2 Infectivity
FDA-2020-D-1824	CDER	Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment
FDA-2020-D-1414	CDER	Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency Guidance for IRBs and Clinical Investigators

FDA-2020-D-1057	CDER	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry
FDA-2021-D-0409	CDER	COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention
FDA-2020-D-1136	CDER	Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency Guidance for Industry
FDA-2020-D-1136	CDER	COVID-19 Container Closure System and Component Changes: Glass Vials and Stoppers Guidance for Industry
FDA-2020-D-1136	CDER	Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency
FDA-2020-D-1138	CDRH	Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency[6]
FDA-2020-D-1138	CDRH	Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)
FDA-2020-D-1138	CDRH	Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
FDA-2020-D-1138	CDRH	Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)
FDA-2020-D-1139	CFSAN	Returning Refrigerated Transport Vehicles and Refrigerated Storage Units to Food Uses After Using Them to Preserve Human Remains During the COVID-19 Pandemic
FDA-2020-D-1108	CFSAN	Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency
FDA-2020-D-1304	CFSAN	Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency
FDA-2020-D-1140	CVM	CVM GFI #271 Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency

V. Other COVID-19 Related Guidance Documents

FDA also has issued the four guidance documents listed in table 4 whose policies and recommendations have supported COVID-19 response efforts, but whose duration is not tied to the COVID-19 PHE declaration, and will remain in effect after expiration of the COVID-19 PHE declaration. In January 2023, FDA revised the two guidances marked with an asterisk in table 4 to state their policies are intended to remain in effect only for the duration of the declaration under section 564 of the FD&C Act by the Secretary of HHS on February 4, 2020, declaring that

[6] FDA is revising the guidance "Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)" to split it into two separate guidance documents, each with identical policies to the corresponding parts of the September 2021 version. Concurrent with issuance of this guidance addressing face masks and barrier face coverings, FDA also is issuing "Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency." That guidance is listed in table 2 of this notice.

circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) (85 FR 7316). These guidances previously stated that they were intended to remain in effect only for the duration of the PHE declaration.

Table 4.--Other COVID-19-Related Guidance Documents

Docket No.	Lead Center	Title of Guidance
FDA-2007-D-0369	CDER	Product-Specific Guidances for Chloroquine and Hydroxychloroquine
FDA-2008-D-0610	CDER	Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic
FDA-2020-D-0987	CDRH	Policy for Coronavirus Disease-2019 Tests (Revised)*
FDA-2020-D-0987	CDRH	Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests*

VI. Electronic Access

Persons with access to the internet may obtain the guidances listed in this notice at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders or https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

Dated: March 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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